

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
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Bernard BENE et al.)	Group Art Unit: 1797
)	
Application No.: 10/526,498)	Examiner: Bass, Dirk R.
)	
Filed: September 29, 2005)	Confirmation No.: 7337
)	
For: CONTROL APPARATUS AND)	Mail Stop After Final
CONTROL METHOD FOR A BLOOD)	
TREATMENT EQUIPMENT)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of the rejections set forth in the Final Office Action mailed on December 17, 2009. Applicant submits that (1) the application has been at least twice rejected; (2) this request is being filed concurrently with a Notice of Appeal; (3) this request is being filed prior to an Appeal Brief; and (4) this request is five or less pages in length, all in accordance with the guidelines set forth in the Official Gazette Notice of July 12, 2005. Applicant requests the prompt review of the Examiner's rejections set forth in the Office Action.

I. Status Of the Claims

In the Final Office Action dated December 17, 2009, the Examiner rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,258,027 to Sternby ("*Sternby*"); and rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,011,384 to Goux ("*Goux*").

II. The Rejection Of Claims 4-17, 20-44, And 60-62 Under 35 U.S.C. § 102(b) Is Legally Deficient Because The Examiner Has Refused To Consider Each And Every Element Of The Claims.

In the Advisory Action mailed June 1, 2010, the Examiner again contends that the claims "are replete with functional and intended use language that does not structurally differentiate the

controller.” (Advisory Action at 2.) The Examiner further contends that “it has been held that an apparatus must be distinguished from the prior art in terms of *structure rather than function*.”

(Id.) Applicant respectfully submits that the Office Action has misunderstood and misapplied the standards for functional language in relation to programmable computers/controllers.

The U.S. Court of Appeals for the Federal Circuit has clearly stated the programmed operations of a processor (i.e., **a computer/controller**) define structure. Citing, *Application of Bernhart, In re Lowry* stated that:

[t]here is one further rationale used by both the board and the examiner, namely, that the provision of new signals to be stored by the computer does not make it a new machine, i.e. it is structurally the same, no matter how new, useful and unobvious the result.... To this question we say that if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed. (Emphasis added.)

In re Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (citing *In re Bernhart*, 57 C.C.P.A. 737, 417 F.2d 1395, 1400, 163 USPQ 611, 615-16 (CCPA 1969)).

Per the M.P.E.P., it is well established that an “[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought.” M.P.E.P. § 2173.01.

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

M.P.E.P. § 2173.05(g). Accordingly, the claims’ recitation of a controller that is configured or programmed to perform one or more functions *physically* distinguishes the claim from the prior art and must be considered. The Examiner’s refusal to examine and give patentable weight to

the limitations of the claims is wholly improper as shown by the M.P.E.P. and Federal Circuit law.

III. Sternby and Goux Do Not Disclose Each and Every Element Of The Claims.

Sternby does not disclose a controller configured to “compare said calculated dialysis dose $K \cdot T_{Ti}$ to at least a total dialysis dosage value $K \cdot T_p$ to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment,” as recited in independent claim 60. Additionally, *Sternby* does not disclose a controller configured to determine “at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p ,” as recited in independent claim 60. Rather, *Sternby* merely discloses “assessing the dialysis treatment on-line to determine the efficiency, the delivered dose, pre and post total urea masses in the body, the urea generation rate, the volume of distribution of urea in the body (for example by taking a blood sample for determining the urea concentration in the blood), and still further parameters and variables.” (Col 12, lines 32-37.) Thus, *Sternby* does not disclose each and every one of the claimed features.

Goux is directed to the calculation of clearance or of dialysance. Specifically, the method of *Goux* includes:

steps of flowing through the exchanger a treatment liquid having a concentration characteristic (C_d) and of varying the value of the characteristic (C_d) upstream of the exchanger for a time at the end of which the characteristic (C_d) is returned to a nominal value. A plurality of values adopted by the characteristic (C_d) downstream of the exchanger in response to the upstream variation is measured and stored in memory. The area (S_{out}) of a downstream perturbation region is determined, which is bounded by a baseline and a curve representing the variation of the measured values with respect to time. Then, the parameter (D , K , Kt/v , C_{bin}) indicative of the effectiveness of the treatment is calculated using the area (S_{in}) beneath the upstream curve and an area beneath an upstream curve.

(Abstract.) However, *Goux* does not disclose a controller configured to “compare said calculated dialysis dose $K \cdot T_{Ti}$ to at least a total dialysis dosage value $K \cdot T_p$ to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment,” as recited in independent claim 60. Additionally, *Goux* does not disclose a controller configured to determine “at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value $K T_p$,” as recited in independent claim 60. Thus, *Goux* does not disclose each and every one of the claimed features.

Applicant notes that dialysance (or clearance) and dialysis dose are distinct parameters representative of distinct concepts. Dialysance and clearance are expressions of the instant efficiency of the treatment. By contrast, dialysis dose is an expression of the cumulated blood depuration from undesired solutes over time.

As recited in independent claim 60, the controller is configured to compare the calculated dialysis dose $K \cdot T_{Ti}$ to the total dialysis dosage value $K \cdot T_p$ to be achieved at the end of the treatment. With this comparison, the controller can ensure that the desired total dialysis dose $K \cdot T_p$ will be delivered by the end of the treatment time.

Independent claim 62 is also patentable over the cited references. The concept behind the subject matter of independent claim 62 is that of a controller programmed to achieve two targets at the same time, namely a desired total weight loss (W_{Lp}) for the patient and a desired total dialysis dosage (K_{Tp}). Applicant notes that according to independent claim 62, a ratio R between W_{Lp} / K_{Tp} is created. At each time interval, the controller controls the fluid removal rate UF_{Ti} so that the ratio between fluid removal rate and instantaneous measured clearance (or dialysance), i.e. UF_{Ti} / K_{Ti} , is also kept equal to R .

Clearance and fluid removal rate are the derivatives over time respectively of W_{Lp} and K_{Tp} . As actual clearance and actual fluid removal rate are kept equal to R at each instant, the two targets W_{Lp} and K_{Tp} will both be achieved with no need to set or calculate a treatment time.

Sternby does not disclose a controller configured to "control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i ," as recited in independent claim 62. *Goux* also does not disclose a controller configured to "control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i ," as recited in independent claim 62.

Accordingly, independent claims 60 and 62 are allowable over *Sternby* and *Goux*. Claims 4, 6-17, 20-25, and 27-44 are allowable at least due to their dependence from claim 60.

IV. Conclusion

For the foregoing reasons, in addition to the reasons in the Reply to Final Office Action filed May 14, 2010, Applicant submits that the rejection of the claims includes factual and legal deficiencies entitling Applicant to a pre-appeal brief review of the Final Office Action. Applicant requests that the rejection be withdrawn and the claims allowed. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account No. 06-0916.

Respectfully submitted,

Dated: June 16, 2010

By: /Aaron L. Parker/
Aaron L. Parker
Reg. No. 50,785